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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,152	01/31/2002	Shuji Saitoh	020058	5985

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ARMSTRONG, WESTERMAN & HATTORI, LLP
1725 K STREET, NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,152

Applicant(s)

Saitoh et al

Examiner

A. R. SALMI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 31, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1-6 are pending.

Raw Sequence Listing have been entered.

Notice of draftsman's patent drawing review (PTO 948) is enclosed.

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite, the intended region or regions where the F protein maybe inserted is not defined. Is the intent to insert the F protein in essential regions of herpesvirus of turkey? This affects the dependent claims.

Claim 2 is vague and indefinite for recitation of "non-coding, interORF region" the intended metes and bounds of the said region is not defined. Is the UL55 region intended?

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the antigens of "avian herpesvirus" wherein the protective immunity is induced against is/are not defined. This affect claim 5.

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Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: when to apply the vaccine, how to apply, the effective amount, etc... This affect claim 5.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship of Newcastle with other “avian herpesvirus” antigens is/are not defined. This affect claim 5.

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for turkey herpesvirus (HVT) having promoter identified as SEQ ID NO: 1 being capable of expressing F protein of Newcastle disease virus (NDV) being inserted into a region between UL45 and UL46 of HVT capable of inducing protective response against Newcastle disease virus (NDV), does not reasonably provide enablement for (1) insertion of F gene in all regions of HVT in general, or “inter-Orf region” in particular (2) method of polyvalent vaccine wherein Newcastle disease virus as well as any and all antigens of avian herpesvirus are to induce protective response. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention

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commensurate in scope with these claims. This field is considered to be highly unpredictable, and it is the disclosure that should teach one of ordinary skill in the art to make and use the invention absent any undue experimentation. The specification does not provide adequate teaching for all regions where a suitable insertion of F gene of NDV can be inserted. If suitable region(s) is/are not taught the vector maybe ineffective since it may become disabled and no expression would take place. In addition, not all non-essential regions are identified where a successful insertion can be made. Absent teaching undue experimentation would be required of one of ordinary skill in the art to enable the claimed invention. Applicants own disclosure is used as evidence for unpredictability of the field, see page 3 of the specification. However, the scope of the claimed invention is not reflective of the disclosure, and absent proper teaching undue experimentation would be required to enable the full scope of the invention. Moreover, there is no teaching presented for a method of polyvalent vaccine, Applicants assertion that the backbone of the expression vector would induce protective response is noted. However, this is not a proper teaching since the expression vector by its very nature is expressing the F antigen of the NDV, and in order to be a sufficient vector its suppose to express the F antigen in sufficient quantity where it would induce protective response. Hence, if the vectors' backbone is suppose to be acting as an antigen then a scenario has to be contemplated wherein the vectors' backbone induces immune response and is digested before the F antigen of NDV is ever expressed or induces any immune response. Still further, there is no teaching as to what antigens of backbone are being expressed and whether or not the immune response is directed against structural

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proteins or non-structural proteins. Therefore, since the specification does not provide adequate teaching for a method of polyvalent vaccine undue experimentation would be required to enable the full scope of the invention. In addition, with regard to an unpredictable field, the limited teaching of the specification does not constitute an adequate disclosure. . See *Fiers v. Revel* (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001-1007). For example, the CAFC stated that “It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement.” (See page 1005 of the decision). This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. Applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al (WO 99/18215).

Saito et al in the above cited patent detailed a construction of turkey herpesvirus (HVT) expression vector for expression of wide variety of antigens into a region between UL45 and UL46 (see page 4, 1st full paragraph, and page 7). They also taught insertion of Newcastle disease virus (NDV) antigens including F antigen into HVT (see page 9, bottom of the page). Moreover, they taught utilization of wide variety of promoters including the chicken beta-actin promoter that is now being claimed (see page 10, bottom of the page). This differs only with respect to the modification to the promoter. Applicants admit on the record that they deleted the dispensable regions of promoter that was taught by the above cited patent (see page 5 of the current specification). Hence, it is concluded that it would have been obvious to one of skill in the art to modify the promoter taught by the above cited patent by deleting a small region of chicken beta-actin promoter without affecting its ability to transcribe a down stream antigen to be utilized in an expression vector of HVT to express F antigen of NDV to induce immune response in poultry. Applicants at the time of filing would have had access to the above teaching and the cited patent taught all the elements that are utilized in the claimed invention except the modified promoter identified as SEQ ID NO: 1. However, given the level of skill in this art is high, the modification of the promoter is seen as a design choice, the skilled artisan would not have

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anticipated any unexpected results. Still further, one of skilled in the art at the time of filing would have been motivated by the teaching of Saito et al to place the MDV antigen in region taught to induce protective response in poultry. Therefore, the invention as a whole is prima facie obvious absent unexpected results.

No claims are allowed.

Conclusion

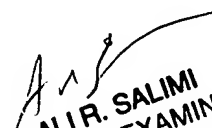
Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A. R. Salimi

2/26/2003


ALI R. SALIMI
PRIMARY EXAMINER